



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|------------------------|---------------------|------------------|
| 10/752,135 | 01/06/2004 | David E. Francischelli | P-8922.06 | 3918 |
| 27581 | 7590 | 09/16/2009 | | |
| MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924 | | | | |
| EXAMINER | | | | |
| PEFFLEY, MICHAEL F | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3739 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 09/16/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/752,135
Filing Date: January 06, 2004
Appellant(s): FRANCISCHELLI ET AL.

Rudolph P. Hofmann
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 18, 2009 appealing from the Office action mailed February 21, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

NEW GROUND(S) OF REJECTION

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stern (5,443,363) in view of the teachings of Nagai et al (5,172,949) and Taylor (6,113,592).

It is noted that claim 20 was erroneously left off the statement of rejection in previous Office actions, but that claim 20 is substantially similar in scope to Independent

claim 1 and that the art used to reject claim 1 reads on the limitations of claim 20 in the same manner.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

| | | |
|-----------|-------------|---------|
| 5,443,463 | STERN et al | 8-1995 |
| 6,113,592 | TAYLOR | 9-2000 |
| 5,647,868 | CHINN | 7-1997 |
| 5,172,949 | NAGAI et al | 12-1992 |
| 4,682,605 | HOFFMAN | 7-1987 |

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 21, 22, 25 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al (5,443,463) in view of the teaching of Taylor (6,113,592).

Stern et al discloses a system comprising an ablation apparatus (10) having first and second jaws (20,30). Energy is delivered to a first side of tissue via electrodes (21), and an array of temperature sensors (31) in close proximity are provided on the other jaw to sense temperature on the opposite side of tissue (Figure 1A). An output device (i.e. computer 114) is used to control the output of RF energy in response to the sensed temperature. In as much as applicant's specification teaches that temperature provides an indication of lesion transmuralty, the examiner maintains that the Stern et al system is inherently adapted to provide an indication of transmuralty of the lesion (i.e.

coagulation zone) since it is monitoring tissue temperature. As seen in Figures 2B and 6, the sensors are provided in the form of a grid. Stern et al fail to specifically disclose that the output device provides for continuous indication of lesion transmural.

Taylor discloses another apparatus for performing transmural lesions, and specifically disclose using temperature monitoring to inform the user of the progress of the lesion. In particular, Taylor discloses a computer (250) having a display (251) for continuously showing the temperature progress as an indication of lesion transmural. The display may be used to show data, images or temperature curves indicative of the progression of the lesion.

To have provided the Stern et al system, which includes temperature sensors and a computer for analyzing and controlling operating parameters, with a means to provide a continuous display of the data to inform the user of the transmural of the lesion being created would have been an obvious consideration for one of ordinary skill in the art since Taylor teach that it is known to use a display means to provide a continuous indication of lesion transmural.

The rejection of claim 20 below under 35 U.S.C. 103(a) as being unpatentable over Stern (5,443,363) in view of the teachings of Nagai et al (5,172,949) and Taylor (6,113,592) is a new grounds of rejection.

Claims 1-4, 6-9, 12, 16, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al (5,443,463) in view of the teachings of Nagai et al (5,172,949) and Taylor (6,113,592).

Stern et al has been addressed previously. While Stern et al teaches of providing energy to one side of tissue and monitoring temperature on an opposite side of tissue, there is no specific teaching of using suction to hold the tissue on the working surface as recited in claim 1. Also, there is no specific disclosure of an output device that provides continuous indication of the transmural of the lesion.

Nagai et al, as addressed in the previous Office action, discloses that it is known to provide a combination suction and temperature sensing element to hold a working surface in contact with the device for monitoring temperature.

And as addressed above, Taylor discloses another apparatus for performing transmural lesions, and specifically disclose using temperature monitoring to inform the user of the progress of the lesion. In particular, Taylor discloses a computer (250) having a display (251) for continuously showing the temperature progress as an indication of lesion transmural. The display may be used to show data, images or temperature curves indicative of the progression of the lesion.

To have provided the Stern et al temperature monitoring jaw with a suction source associated with the temperature sensors for holding tissue during treatment and tissue temperature monitoring would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Nagai et al. To have further provided the Stern et al system with a means to provide continuous display of the data to inform the user of lesion transmural would have been an obvious modification for the skilled artisan in view of the teaching of Taylor.

Claims 5, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al ('463), Taylor ('592) and Nagai et al ('949) as applied to claims 1 and 4 above, and further in view of Chinn (5,647,868).

The combination of the Stern et al device with the Nagai et al and Taylor teachings has been addressed. While Stern et al disclose a computer system for controlling and displaying data, there is no specific teaching that a representation of the device is used to indicate measured parameters such as temperature (i.e. lesion transmuralty).

Chinn discloses an analogous RF treatment system that uses temperature sensing to control RF output. In particular, Chinn teaches that it is known to provide a display that includes a visual representation of the device to show sensed and performance output parameters during a surgical procedure. This allows the user to visually acquire data of the system during the procedure.

To have provided the Stern et al device, as modified by the teachings of Nagai et al and Taylor, with a virtual display to provide a visual representation of the system and working parameters such as temperature would have been an obvious modification for one of ordinary skill in the art since Chinn teach it is known to use such a display to assist in analogous surgical procedures.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al ('463), Taylor ('592) and Nagai et al ('949) as applied to claim 1 above, and further in view of Hoffman (4,682,605).

Stern et al fail to disclose the use of liquid crystals and/or temperature sensing chemicals to monitor temperature. The examiner maintains that the use of any well-known temperature sensing mechanism in the Stern et al device would be an obvious substitution.

To that end, Hoffman et al disclose that it is old and well-known to use temperature sensing devices such as liquid crystals and temperature sensing chemicals to provide detailed temperature mapping of tissue.

To have provided the Stern et al device, as modified by the teachings of Nagai et al and Taylor, with liquid crystals or temperature sensing chemicals as the temperature sensing grid on the second jaw of the device would have been an obvious modification for one of ordinary skill in the art since Hoffman fairly teaches that it is known to use such means for tissue temperature monitoring.

Claims 23, 24 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al ('463) and Taylor ('592) in view of the teaching of Chinn ('868).

Again, Taylor discloses a computer system for controlling and displaying data that may be combined with the Stern et al system, but there is no specific teaching that a representation of the device is used to indicate measured parameters such as temperature.

Chinn discloses an analogous RF treatment system that uses temperature sensing to control RF output. In particular, Chinn teaches that it is known to provide a

display that includes a visual representation of the device to show sensed and performance output parameters during a surgical procedure. This allows the user to visually acquire data of the system during the procedure.

To have provided the Stern et al device, as modified by the teaching of Taylor, with a virtual display to provide a visual representation of the system and working parameters such as temperature would have been an obvious modification for one of ordinary skill in the art since Chinn teach it is known to use such a display to assist in analogous surgical procedures.

(10) Response to Argument

Regarding independent claim 21, applicant asserts that Stern fails to show or make obvious an array of temperature sensors that are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue. The examiner disagrees. As clearly shown in the Figures, Stern shows temperature sensors (31) provided opposite electrodes (21), the sensors being in close proximity to each other. It is noted that there is no disclosure in applicant's specification of what defines "close proximity", nor is there any critical separation distances disclosed that are necessary to perform the function of detecting continuous temperature along tissue. The examiner maintains the Stern temperature sensors are appropriately spaced along the forceps jaw so as to be inherently capable of effectively detecting continuous temperature along the tissue. The applicant then goes on to assert that the temperature in the spaces between the electrodes are unknown. Again, applicant has not provided any critical spacing for the sensors, and applicant's own temperature sensors are

spaced along a member such that there are gaps between the sensors (much like the Stern device). The examiner maintains that given the relative size of the Stern forceps jaw (as would generally be known in the art) and applicant's probe, and the number of sensors located on each device, that the relative spacing for the electrodes is substantially similar. Applicant has provided no reason why the spaced sensors in the application claims are suitable to monitor continuous temperature and the spaced sensors of the Stern device would be incapable of such a function. The examiner maintains the Stern sensors do effectively detect a continuous temperature along the length of the jaw containing the sensors. Taylor is cited as a teaching that it is clearly known to use a display to show tissue temperature during a procedure (see, for example, Figures 10 and 13). The examiner maintains that the display of temperature would inherently be a showing of lesion transmuralty since applicant's disclosure admits of the relationship between temperature and lesion transmuralty. Whether Stern or Taylor specifically associate sensed temperature with lesion transmuralty is immaterial to the rejection since the necessary structure to meet this use is found in the prior art references. Stern discloses a device that creates a linear lesion and includes temperature sensors in close proximity to each other that are inherently capable of detecting continuous temperature. Taylor provides the motivation to provide such a device with an output device (e.g. display) to provide an indication of lesion progress to a user. The examiner maintains the combination of the teachings is properly motivated and provides the necessary structure to meet the claimed invention. Applicant has not substantively argued the merits of claims 22, 25 and 29, but rather has asserted that

they are allowable due to their dependency from claim 21. The examiner maintains the rejection of claim 21 is tenable, and also maintains the rejection of claims 22, 25 and 29.

Regarding claim 1, this claim differs from claim 21 with the inclusion of a suction source for maintaining tissue in contact with the device. Applicant again asserts that the prior art, specifically Taylor and Stern, fails to disclose temperature sensors in close proximity to each other to detect continuous temperature along a second side of tissue. The examiner reasserts the arguments made above with respect to this issue. Applicant has not substantively argued the combination of the Nagai reference other than to maintain that the prior art references fail to show the claimed temperature sensors for detecting continuous temperature.

Claim 20 is substantially identical in scope to claim 1 with only slight modifications to the claim language. As such, the Taylor and Stern references, when further combined with the Nagai et al teaching of providing suction to a clamping device, are deemed to read on claim 20 for the same reasons as addressed previously.

Regarding the remaining dependent claims, applicant has not substantively argued the merits of these claims and has simply maintained the argument that the Stern device in view of the teaching of Taylor fails to disclose the temperature sensing elements in close proximity to each other to effectively detect continuous temperature and to indicate continuous transmural of a lesion. The examiner has previously addressed this topic, and the examiner maintains the rejections of the dependent claims remain tenable.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section (9) above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte dismissal of the appeal* as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

/Michael Peffley/
Primary Examiner, Art Unit 3739

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/DONALD T HAJEC/

Director, Technology Center 3700

Conferees:

/Linda C Dvorak/

Supervisory Patent Examiner, Art Unit 3739

/Tom Hughes/

TQAS, TC 3700

